

PTO-1390 (Rev. 02-2005)

Approved for use through 03/31/2007. OMB 0651-0021

U. S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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|---|---|---|
| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 | | ATTORNEY'S DOCKET NUMBER 60384(71699) |
| | | U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/539212 |
| INTERNATIONAL APPLICATION NO. US03/40344 | INTERNATIONAL FILING DATE 20 December 2003 | PRIORITY DATE CLAIMED 20 December 2002 |
| TITLE OF INVENTION TREATMENT OF METASTATIC COLON CANCER WITH B-SUBUNIT OF SHIGA TOXIN | | |
| APPLICANT(S) FOR DO/EO/US Olga N. Kovbasnjuk et al. | | |

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

- ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
- ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
- ☐ This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below.
- ☐ The US has been elected (Article 31).
- ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
 - ☒ is attached hereto (required only if not communicated by the International Bureau).
 - ☐ has been communicated by the International Bureau.
 - ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
- ☐ An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).
 - ☐ is attached hereto.
 - ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
- ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - ☐ are attached hereto (required only if not communicated by the International Bureau).
 - ☐ have been communicated by the International Bureau.
 - ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - ☐ have not been made and will not be made.
- ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
- ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
- ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 11 to 20 below concern document(s) or information included:

- ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
- ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
- ☒ A preliminary amendment.
- ☐ An Application Data Sheet under 37 CFR 1.76.
- ☐ A substitute specification.
- ☐ A power of attorney and/or change of address letter.
- ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
- ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
- ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
- ☒ Other items or information: Form PCT/IB/308; Form PCT/IB/301; Form PCT/IB/304; First Page of Published Int'l App. no. WO 2004/058158 A2 and Return Receipt Postcard

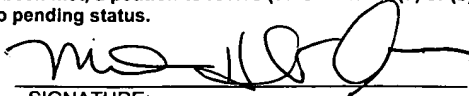
JC20 Rec'd PCT/PTO 17 JUN 2005

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|---|--------------|---|---|
| U.S. APP. NO. 10/539212 | | INTERNATIONAL APPLICATION NO. US03/40344 | ATTORNEY'S DOCKET NUMBER 60384(71699) |
| The following fees have been submitted | | CALCULATIONS | PTO USE ONLY |
| 21. <input checked="" type="checkbox"/> Basic national fee | \$300 | \$ 300.00 | |
| 22. <input checked="" type="checkbox"/> Examination fee | | | |
| If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)..... | | | |
| All other situations | | \$ 200.00 | |
| 23. <input checked="" type="checkbox"/> Search fee | | | |
| Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... | | | |
| International Search Report prepared and provided to the Office | | \$ 100.00 | |
| All other situations..... | | \$ 500.00 | |
| TOTAL OF 21, 22 and 23 = | | \$ 600.00 | |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | |
| Total Sheets | Extra sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE |
| 51 - 100 = | /50 = | | x \$250.00 |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492 (e)). | | \$ 130.00 | |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE |
| Total claims | 17 - 20 = | x | \$ 0.00 |
| Independent claims | 2 - 3 = | x | \$ 0.00 |
| MULTIPLE DEPENDENT CLAIM(s) (if applicable) | | + | \$ |
| TOTAL OF ABOVE CALCULATIONS = | | \$ 730.00 | |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. | | \$ 365.00 | |
| SUBTOTAL = | | \$ 365.00 | |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492 (f)). | | + | \$ |
| TOTAL NATIONAL FEE = | | \$ 365.00 | |
| Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property | | + | \$ |
| TOTAL FEES ENCLOSED = | | \$ 365.00 | |
| | | Amount to be refunded: | \$ |
| | | Amount to be charged: | \$ |
| <p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>04-1105</u> in the amount of \$ <u>730.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>04-1105</u>. A duplicate copy of this sheet is enclosed.</p> <p>d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <p>NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the International Application to pending status.</p> <p>SEND ALL CORRESPONDENCE TO:</p> <p>Peter F. Corless EDWARDS & ANGELL, LLP P.O. Box 55874 Boston, Massachusetts 02205 (617) 439-4444 CUSTOMER NUMBER: 49383</p> <p style="text-align: right;">  SIGNATURE: Melissa Hunter-Ensor NAME REGISTRATION NUMBER <u>55,289</u> </p> | | | |

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|---|-----------------------|---|--|--------------------|-----------|-------------|-----------------------|----------------------|--------------------|---------------|------------------|----------|-----|---------------------|--------------|
| <p><i>Effective on 12/08/2004.</i> <i>Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).</i></p> <h2 style="margin: 0;">FEE TRANSMITTAL</h2> <h3 style="margin: 0;">For FY 2005</h3> | | <p>Complete if Known</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td style="width: 50%;">10/539212</td> </tr> <tr> <td>Filing Date</td> <td>Concurrently Herewith</td> </tr> <tr> <td>First Named Inventor</td> <td>Olga N. Kovbasnjuk</td> </tr> <tr> <td>Examiner Name</td> <td>Not Yet Assigned</td> </tr> <tr> <td>Art Unit</td> <td>N/A</td> </tr> <tr> <td>Attorney Docket No.</td> <td>60384(71699)</td> </tr> </table> | | Application Number | 10/539212 | Filing Date | Concurrently Herewith | First Named Inventor | Olga N. Kovbasnjuk | Examiner Name | Not Yet Assigned | Art Unit | N/A | Attorney Docket No. | 60384(71699) |
| Application Number | 10/539212 | | | | | | | | | | | | | | |
| Filing Date | Concurrently Herewith | | | | | | | | | | | | | | |
| First Named Inventor | Olga N. Kovbasnjuk | | | | | | | | | | | | | | |
| Examiner Name | Not Yet Assigned | | | | | | | | | | | | | | |
| Art Unit | N/A | | | | | | | | | | | | | | |
| Attorney Docket No. | 60384(71699) | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27 | | | | | | | | | | | | | | | |
| TOTAL AMOUNT OF PAYMENT | (\$) | 365.00 | | | | | | | | | | | | | |

| | |
|--|--|
| METHOD OF PAYMENT (check all that apply) | |
| <input type="checkbox"/> Check <input type="checkbox"/> Credit Card <input type="checkbox"/> Money Order <input type="checkbox"/> None <input type="checkbox"/> Other (please identify): _____ | |
| <input checked="" type="checkbox"/> Deposit Account Deposit Account Number: <u>04-1105</u> Deposit Account Name: <u>The Johns Hopkins University</u> | |
| For the above-identified deposit account, the Director is hereby authorized to: (check all that apply) | |
| <input checked="" type="checkbox"/> Charge fee(s) indicated below <input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee | |
| <input type="checkbox"/> Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 <input checked="" type="checkbox"/> Credit any overpayments | |

| FEE CALCULATION | | | | | | | |
|---|-------------|-----------------------|-------------|-----------------------|------------------|-----------------------|----------------|
| 1. BASIC FILING, SEARCH, AND EXAMINATION FEES | | | | | | | |
| Application Type | FILING FEES | | SEARCH FEES | | EXAMINATION FEES | | Fees Paid (\$) |
| | Fee (\$) | Small Entity Fee (\$) | Fee (\$) | Small Entity Fee (\$) | Fee (\$) | Small Entity Fee (\$) | |
| Utility | 300 | 150 | 500 | 250 | 200 | 100 | |
| Design | 200 | 100 | 100 | 50 | 130 | 65 | |
| Plant | 200 | 100 | 300 | 150 | 160 | 80 | |
| Reissue | 300 | 150 | 500 | 250 | 600 | 300 | |
| Provisional | 200 | 100 | 0 | 0 | 0 | 0 | |
| 2. EXCESS CLAIM FEES | | | | | | | |
| Fee Description | Fee (\$) | Small Entity Fee (\$) | | | | | |
| Each claim over 20 (including Reissues) | 50 | 25 | | | | | |
| Each independent claim over 3 (including Reissues) | 200 | 100 | | | | | |
| Multiple dependent claims | 360 | 180 | | | | | |
| <u>Total Claims</u> <u>Extra Claims</u> <u>Fee (\$)</u> <u>Fee Paid (\$)</u> | | | | | | | |
| 17 - 20 = x = | | | | | | | |
| <u>Indep. Claims</u> <u>Extra Claims</u> <u>Fee (\$)</u> <u>Fee Paid (\$)</u> | | | | | | | |
| 2 - 3 = x = | | | | | | | |
| 3. APPLICATION SIZE FEE | | | | | | | |
| If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). | | | | | | | |
| <u>Total Sheets</u> <u>Extra Sheets</u> <u>Number of each additional 50 or fraction thereof</u> <u>Fee (\$)</u> <u>Fee Paid (\$)</u> | | | | | | | |
| 49 - 100 = /50 (round up to a whole number) x = | | | | | | | |
| 4. OTHER FEE(S) | | | | | | | |
| Non-English Specification, \$130 fee (no small entity discount) | | | | | | | 150.00 |
| Other (e.g., late filing surcharge): 2631 Basic National Stage fee | | | | | | | 100.00 |
| 2633 National Stage Examination Fee - all other ... | | | | | | | 50.00 |
| 2641 National Stage Search Fee - U.S. was the ISA | | | | | | | 65.00 |
| 2617 National Stage oath or declaration after thirty ... | | | | | | | |

| | | | |
|---------------------|----------------------|-----------------------------------|--------|
| SUBMITTED BY | | | |
| Signature | | Registration No. (Attorney/Agent) | 55,289 |
| Telephone | (617) 439-4444 | | |
| Name (Print/Type) | Melissa Hunter-Ensor | | |
| Date | June 17, 2005 | | |

| | |
|---|----------------------------------|
| I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 492338699 US, in an envelope addressed to: MS PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below. | |
| Dated: June 17, 2005 | Signature: (Eileen M. Woodbury) |

10/539212

JC20 Rec'd PCT/PTO 17 JUN 2005

Application No. (if known): Not Yet Assigned

Attorney Docket No.: 60384(71699)

Certificate of Express Mailing Under 37 CFR 1.10

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on June 17, 2005
Date



Signature

Eileen M. Woodbury

Typed or printed name of person signing Certificate

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Fee Transmittal (1 page)
Transmittal Letter to the United States Designated-Elected Office (2 pages)
Preliminary Amendment (6 pages)
Copy of the International application (49 pages)
Drawings (8 Sheets)
Oath or declaration of the inventor(s) (4 pages)
Form PCT/IB/308 (1 page)
Form PCT/IB/301 (2 pages)
Form PCT/IB/304 (1 page)
First Page of Published Int'l App. WO 2004/058158 A2 (1 page)
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